

JUN 1 8 2001

January 10, 2001
Flowable Composite

510(k) Summary

K011211

Trade Name: Flowable Composite

Sponsor: DMG USA, Inc.
414 South State Street
Dover, DE 19901
Registration # not yet assigned

Device Generic Name: Tooth shade resin material

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II (76EBF).

Predicate Devices: The proposed Flowable Composite material is substantially equivalent to the Zenith Flowable Composite material marketed by Foremost Dental Manufacturing, Inc., which was cleared for marketing by FDA in K970683.

Product Description:

The Flowable Composite material is a visible light-cured dental restorative that contains fluoride. This reduced viscosity dental composite is designed for use in creating restorations as well as an add-on or repair material for provisional crowns & bridges and for chairside pickup of attachment components.

Indications for Use:

The DMG USA Flowable Composite is a visible light-cured material for use as an aesthetic anterior restoration or base restoration under posterior or anterior composites. Flowable Composite is also indicated as an add-on or repair material for provisional crowns & bridges and for incorporation of most mechanically anchored attachment components into the acrylic base of an overdenture or partial denture.

Safety and Performance:

Substantial equivalence for this device was based on similarities in materials, design and performance characteristics. No safety or performance testing was required to establish substantial equivalence for the Flowable Composite

Conclusion:

Based on the indications for use, technological characteristics, and comparison to predicate devices, the DMG USA Flowable Composite has been shown to be safe and effective for its intended use.

000023



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 8 2001

DMG USA, Incorporated
C/O Ms. Pamela Papineau
Consultant
Delphi Medical Device Consulting
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K011211
Trade/Device Name: Flowable Composite
Regulation Number: 872.3690
Regulatory Class: II
Product Code: EBF
Dated: January 10, 2001
Received: April 19, 2001

Dear Ms. Paineau:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

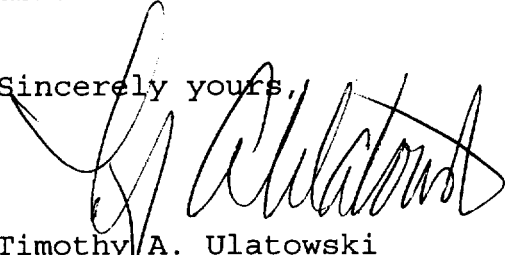
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 1 of 1

510(k) Number (if known): K011211

Device Name: Flowable Composite

Indications for Use:

Flowable Composite is a visible light cure composite material indicated for use as an aesthetic anterior restoration or base restoration under posterior or anterior composites. Flowable Composite is also indicated as an add-on or repair material for provisional crown & bridge materials and for incorporation of most mechanically anchored attachment components into the acrylic base of an overdenture or partial denture.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-the -Counter Use ☐

Suzanne Runnes

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K011211

CO